IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION — MDL No. 2326

THIS DOCUMENT RELATES TO:

Hanna Wilkerson,

v.

Boston Scientific Corporation,

Civil Action File Number: 2:13-cv-04505

Rule 26 Expert Report – Ricardo Caraballo, M.D., F.A.C.O.G.

I. Qualifications

I am a female pelvic medicine and reconstructive surgery specialist licensed to practice in New Jersey. My clinical practice focuses on female pelvic medicine and reconstructive surgery, with a special interest in vaginal reconstruction. I have extensive experience treating women suffering from stress urinary incontinence (SUI) and pelvic organ prolapse (POP). In treating SUI and POP, I use surgical procedures that employ polypropylene mesh devices, as well as non-mesh procedures. I have extensive experience with Boston Scientific's products for treating SUI – primarily the Advantage Fit Sling System. I also have extensive experience teaching minimally invasive surgical techniques and procedures – including implantation of the Advantage Fit Sling System – to physicians from across the United States.

I received my Doctor of Medicine degree from Temple University School of Medicine in 1994. I completed my residency in Obstetrics and Gynecology in 1998 at Cooper Hospital / University Medical Center (Camden, NJ), and served as chief resident for the Obstetrics and Gynecology Residency Program during the final year of my residency. I have been board-certified in Obstetrics and Gynecology since 2001. I received my Female Pelvic Medicine and Reconstructive Surgery Certification in 2013. I am the Associate Fellowship Program Director for Female Pelvic Medicine and Reconstructive Surgery and an Assistant Professor of Obstetrics and Gynecology at Cooper Medical School of Rowan University. Among other professional associations, I am a fellow of the American Congress of Obstetricians and Gynecologists, and a member

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of the American Urogynecologic Society, the International Urogynecological Association, and the Society of Gynecologic Surgeons.

The following report contains my opinions specific to the Hanna Wilkerson case. I hold all opinions to a reasonable degree of medical and scientific certainty. My opinions are based on my education, training, clinical experience, review of medical and scientific literature, information presented at various medical forums, information from Ms. Wilkerson's expert witnesses, and review of records and materials specific to Ms. Wilkerson.

My compensation in this matter is $450 per hour. My *curriculum vitae* , which sets out my qualifications and list of publications, is affixed to this report as Exhibit A. A list of materials that I reviewed before forming my opinions is attached as Exhibit B. As of the date of this report, during the past four years, I have not testified as an expert witness in any other cases.

II. Overview of Stress Urinary Incontinence and Pelvic Organ Prolapse

Stress urinary incontinence (SUI) is the observation of involuntary leakage from the urethra synchronous with effort or physical exertion, or upon sneezing or coughing – also known as "stress activities." SUI is often caused by hypermobility of the urethra. SUI occurs when support structures inside the vagina that surround and support the urethra weaken. During stress activities, an increase in pressure in the abdomen causes the urethra to move below the abdominal cavity, leading to involuntary leakage. SUI is very common, especially among women who have had children. A woman's lifetime risk of developing urinary incontinence of some form is at least 50%, with many of these cases involving SUI.[1]

SUI can have a devastating effect on a woman's quality of life. Women suffering from SUI may need to wear absorbent sanitary pads or even adult diapers. These women may experience urinary leakage onto clothing and the body, urination during intercourse, and foul odors. Emotional effects of SUI often include avoidance of personal and professional situations, negative effect on sexual relations, feelings of self-consciousness, depression, and negative body image. SUI usually does not improve without treatment and often worsens over time.

Pelvic organ prolapse (POP) occurs when the connective tissue and/or muscular tissue that support the pelvic organs (bladder, uterus, rectum, small intestines, and vaginal vault) weaken, allowing the pelvic organs to descend into the vaginal canal. In severe cases of POP, pelvic organs may actually protrude beyond the vaginal opening. POP is

[1] Richter, H, et al. Retropubic versus transobturator midurethral slings for stress incontinence. New Eng J Med 2010; 362:2066-76.

graded by severity – from Stage 0 (no prolapse) to Stage 4 (complete prolapse). In my experience, many women seek medical treatment once their condition reaches Stage 2.

III. Treatment Options for Stress Urinary Incontinence

A. Non-Surgical Options

Non-surgical options for women with SUI include timed voiding, "Kegel" strengthening exercises, physical therapy, and lifestyle modifications such as weight loss. In my experience, these non-surgical options are not always effective in treating or even managing SUI. Many women with bothersome SUI require surgery to relieve their symptoms.

B. Historical Surgical Procedures

One significant early SUI surgery was the MMK procedure (Marshall, Marchetti, Krantz). This procedure required an abdominal incision and placement of permanent stiches into the pelvis. Subsequent procedures for treating SUI included needle suspensions of the vagina (e.g., Perrera-Raz suspension); the Burch procedure (a modification of the MMK), which involved placing permanent stitches into the Cooper's ligament; and bladder neck slings.

The MMK and Burch were each once considered to be the "gold standard" of SUI treatment, with an approximate 70% success rate at five years.[2] These procedures remain appropriate options for some patients. However, these procedures involve relatively high morbidity rates, as well as invasive abdominal surgeries that increase the risk of injury and complications.

C. Mid-Urethral Slings

In 1996, the FDA cleared the first mid-urethral sling device constructed of polypropylene mesh. This device was known as trans-vaginal tape (TVT). TVT had a retropubic design, meaning that it looped through the retropubic space. It was made from "Type 1" polypropylene mesh, which means that it was a monofilament, macroporous construction.[3] Mid-urethral slings are designed to be permanent implants that facilitate tissue ingrowth.

Compared to historical surgical procedures that required more invasive entry into the retropubic space, more recent approaches have decreased the risk of bowel and bladder injury, and resulted in less pain, shorter hospitalization, faster return to usual

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[2] Lapitan MC, et al. Open retropubic colposuspension for urinary incontinence in women: a short version Cochrane review. Neurourol. Urodyn. 2009; 28(6):472-80.

[3] Amid P. Classification of biomaterials and their related complications in abdominal wall surgery. Hernia. 1997; 1(1):15–21.

activities, and reduced costs.[4] Mid-urethral slings have supplanted the Burch procedure – the former gold standard in SUI surgery – as a more effective option, with fewer complications, and better quality-of-life results.[5]

Boston Scientific received FDA clearance for the placement of surgical mesh via a percutaneous approach or transvaginal approach in 2002. After this clearance, the Advantage was Boston Scientific's first mid-urethral sling. The Advantage slings, like TVT, have a retropubic design and are made from Type 1 polypropylene mesh. When the Advantage sling was first fully launched in the United States in 2003, multiple long-term studies had already shown that a retropubic mid-urethral sling constructed of Type 1 polypropylene mesh was the safest and most effective design and construction available for treating SUI, with cure and complication rates that compared favorably to non-mesh SUI surgeries.[6] Boston Scientific launched the Advantage Fit in the United States in 2008. The Advantage Fit was made from the same Type 1 polypropylene mesh as the Advantage and used the same retropubic approach, but incorporated several design improvements from the Advantage.

Ms. Wilkerson was implanted with an Advantage Fit sling on March 9, 2010. At the time of Ms. Wilkerson's surgery, long-term data existed supporting the use of mid-urethral slings constructed from Type 1 polypropylene mesh, and was well known in the gynecologic community.[7] Additional data available today further establish the long-term safety and efficacy of polypropylene slings like the Advantage Fit.[8] Long-term data also illustrates the superiority of mid-urethral slings like the Advantage Fit over traditional

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[4] AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 2014).

[5] Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women (Review). The Cochrane Collaboration 2010; 1:1-48; Kenton K, et al. Outcomes and Complications of Burch, Fascial, and Midurethral Slings. ICS. 2013; Abstract #182.

[6] Ulmsten U, et al. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br. J. Obstet. Gynaecol. 1999; 106:345-50; Olsson I, et al. A three-year postoperative evaluation of tension-free vaginal tape. Gynecol & Obstet Invest. 1999; 48:267-69; Merlin T, et al., A systematic review of tension-free urethropexy for stress urinary incontinence: intravaginal slingplasty and the tension-free vaginal tape procedures, BJU Int. 2001; 88:871-80; Liapis A, et al., Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women, Eur Urol. 2002; 41:469-73.

[7] Olson I, et al. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence, Int Urogynecol J. 2010; 21:679-83; Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol. 2008; 53:401-10; Song PH, et al., The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence. BJU Int. 2009, 104:1113-17.

[8] Basu M, et al. Three-year results from a randomized trial of a retropubic mid-urethral sling versus the Miniarc sling for stress urinary incontinence. Int Urogynecol J. 2013; 24(12):2059-64; Serati M, et al. Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012; 61:939-46; Renganathan A, et al., A series of Advantage suburethral slings. J of Obstet & Gynaecol. 2011; 31:521-23; Tarcan T, et al., Safety and Efficacy of Retropubic or Transobturator Midurethral Slings in a Randomized Cohort of Turkish Women. Urologia Internationalis. 2014; 10:1159-63.

incontinence surgery.[9] The FDA's Obstetrics & Gynecology Devices Panel has also acknowledged the safety and efficacy of mid-urethral slings.[10]

Citing this data and clinical experience, multiple leading medical organizations dedicated to the treatment of female pelvic disorders have endorsed the safety and efficacy of mid-urethral slings:

- In January 2014, the American Urogynecologic Society (AUGS) issued a joint position statement with the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) that stated as follows: "Full-length midurethral slings, both retropubic and transobturator . . . are safe and effective relative to other treatment options and remain the leading treatment option and the current gold standard for stress incontinence surgery."[11]

- The American Urological Association (AUA) has stated that "[e]xtensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries."[12]

- Most recently, the International Urogynecological Association (IUGA) issued a position statement in support of mid-urethral slings for the treatment of SUI, citing "robust evidence to support the use of MUS from over 2,000 publications making this treatment the most extensively reviewed and evaluated procedure for female stress urinary incontinence now in use."[13]

I concur with the views set out in each of these position statements. I believe that mid-urethral slings constructed from Type 1 polypropylene mesh represent the "gold standard" and the standard of care in treating women with SUI. I also have extensive experience treating my own patients with the Advantage Fit sling. My experience using this device has been overwhelmingly positive. My complication and cure rates following implantation of Advantage Fit slings are superior to the complication and cure rates I

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[9] Ward KL, et al. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 2008; 115:226-233. Jelovsek JE, et al., Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. BJOG 2008; 115:219-25. Novara G, et al., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurthral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010; 58:218-38. Schimpf, MO, et al., Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J of Obstet & Gynec. 2014; 71:e1-e27.

[10] 24-Hour Summary, Surgical Mesh Panel Meeting (Sept. 8-9, 2011), available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM271769.pdf

[11] AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 2014).

[12] AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence.

[13] IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence.

have seen utilizing other therapies and non-mesh slings to treat SUI. The Advantage Fit device is safe and effective for the treatment of SUI.

IV. Risks Associated with Pelvic Floor Surgery for SUI

As with any surgical procedure, operations to correct SUI are associated with certain risks. These risks are influenced by factors such as choice of procedure, skill and experience of the implanting surgeon, and individualized patient factors.

With one exception – exposure (and relatedly, erosion) – the risks associated with implantation of polypropylene mesh to treat SUI are the same as the risks associated with any native tissue repair or biologic graft. All surgeries to treat SUI carry the following known risks, regardless of whether polypropylene mesh is used: injury to blood vessels, nerves, bladder, and/or bowel; infection; pain; dyspareunia; persistent or de novo urinary incontinence; tissue contracture; abscess; urinary dysfunction, including urinary retention; vaginal discharge; nerve injury; detrusor over-activity; constipation; and possible revision surgery.

The term exposure refers to mesh that should be covered by vaginal epithelium but is seen on vaginal examination and/or felt by the patient or her sexual partner. Relatedly, the term "erosion" is sometimes used to refer to mesh that comes into contact with an adjacent organ. Exposure and erosion have been a known and accepted risk in the implantation of synthetic mesh since the inception of these products.[14] In my experience, the majority of incidents of sling mesh exposure are asymptomatic and can be easily treated with topical estrogen cream and/or minor surgical procedures to remove the small pieces of exposed mesh.

None of the risks or complications listed above constitute a defect in Boston Scientific's Advantage Fit sling device, or in the mesh material itself. Moreover, all of the risks and complications identified above are adequately warned of in the Directions For Use (DFU) for the Advantage Fit. These risks are not new. They have been known since the first use of pelvic mesh in 1996 and they should form a part of every discussion that a surgeon has with his or her patient.

In fact, the surgeon who implanted Ms. Wilkerson's Advantage Fit sling – Dr. Kelly Booth – recorded in her medical records that she counseled Ms. Wilkerson concerning the risks of pelvic floor surgery generally, as well as the risk of "mesh erosion." Dr. Booth recorded that "[k]nowing these risks, the patient is willing to proceed," and that all of Ms. Wilkerson's questions were answered. Ms. Wilkerson also signed an informed consent procedure prior to her surgery.

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[14] Julian, T. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall, Am. J. Obstet. & Gynecol 1996; 175:1472-75.

I understand there has been a contention that Boston Scientific should have included rates of complications in its DFU. I am unaware of any medical device that includes rates of complications in its DFU or other product literature. I believe that it would be inappropriate to include these types of numbers because complication rates vary widely, and are influenced by many variables, including surgical skill and patient-specific factors. I believe that it is the responsibility of the surgeon who performs mesh implantation procedures to keep himself or herself apprised of risks specific to the procedures performed in his or her own practice and to counsel patients on complication rates. In fact, Boston Scientific includes this instruction in the DFU for the Advantage Fit: "The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures."

I understand that certain witnesses have criticized Boston Scientific's DFU for not indicating that certain complications might be "permanent." No need exists for such an obvious warning. Surgeons are taught early in medical school that complications associated with surgery might be permanent. This fact is emphasized throughout medical school, residency, and fellowship training.

My long-term experience implanting the Advantage Fit device demonstrates that this device is not associated with any new risks to patients that I had not previously encountered with other pelvic floor surgeries. To the contrary, this device reduced the risk of many complications I have encountered in alternative surgeries designed to treat SUI and provided a safe, effective, and less-invasive alternative to traditional options.

V. Polypropylene Mesh Does Not Contract, but Tissue Contracture Is Accounted for in Design and Warned of in the DFU.

I understand that certain witnesses have opined that the mesh used in Boston Scientific's Advantage Fit device contracts inside the body, causing complications in some cases. Polypropylene mesh itself does not contract inside the body,[15] and I have seen no evidence of mesh contracture in my clinical experience.

Tissue contracture, on the other hand, is a known and expected component of the body's healing process following implantation of mesh devices, or any surgery. Surgeons understand that the tissue ingrowth process will result in some degree of scar contracture. Indeed, the DFU for the Advantage Fit, identify "mesh and/or tissue contracture" as a potential adverse event and warn the user: "Avoid excess tensioning of the mesh when positioning to avoid over correction of the defect."

Literature suggesting that polypropylene mesh contracts relies upon ultrasound images from hernia repairs. These ultrasound images could not accurately distinguish between mesh contraction and tissue contraction.

[15] Dietz HP, et al. Mesh contraction: myth or reality? Am J Obstet Urogynecol 2011; 204:173 e1-4.

In my clinical practice, I have not seen significant complications resulting from tissue contracture. To the contrary, scar contracture is limited, and the overwhelming majority of patients receiving polypropylene mesh slings, including the Advantage Fit, do not report pain beyond the immediate post-operative period.

VI. Polypropylene Is Not Known to Cause Any Adverse Foreign Body Reaction.

Certain witnesses in this case have also opined that once polypropylene mesh is implanted, the body's immune system will initiate a foreign body response that degrades the material and does not stop until the mesh is removed. I believe that these opinions concerning a foreign body reaction are misleading and unsupported.

I have seen no evidence in my many years of clinical experience of polypropylene degradation in vivo caused by a continuous foreign body reaction. Nor is there any evidence from the medical community that polypropylene degrades continuously in vivo.

It is true that the human body initiates a foreign body response when any medical device is implanted. Such a response is expected and is part of the body's normal healing process. This foreign body response does not cause polypropylene mesh to continuously degrade until mesh is removed.[16] Based on my clinical experience, if mesh caused a chronic inflammatory response, I would expect to see higher complication rates associated with the use of polypropylene implants, and I would not expect to see studies demonstrating favorable long-term results associated with the use of polypropylene as a biomaterial.[17] In reality, polypropylene has a long history of safe and effective use in the human body.[18]

VII. The Material Data Safety Sheet Is Irrelevant to the Clinician's Choice of Device in Treating Patients with SUI.

Certain witnesses in this case have offered opinions about a material safety data sheet (MSDS) related to the polypropylene resin used in the manufacture of Boston Scientific's Advantage Fit devices. As a surgeon, I have never consulted an MSDS to evaluate the safety and efficacy of a medical device. Nor have I ever consulted an MSDS when treating or counseling a patient.

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[16] Woodruff A, et al., Histologic Comparison of Pubovaginal Sling Graft Materials: A Comparative Study. Female Urology. 2008; 72(1):85-89.

[17] Serati M, et al. Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up. Eur Urol 2012; 61:939-46. Olsson I., et al. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence. Int Urogynecol J 2010; 21:679-83.

[18] AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 2014).

Based upon my education, training, and experience, it is my opinion that surgeons do not rely upon the MSDS for raw materials used in the devices they implant in patients. Nor does an MSDS form the basis of surgeons' risk-counseling discussions with their patients.

With respect to the MSDS referenced by Ms. Wilkerson's experts, I have not seen any evidence that the medical application caution was added because of any scientific or safety concerns. In fact, AUGS and SUFU have recognized that polypropylene has been used safely and effectively in most surgical sub-specialties over the past five decades.[19] The findings by AUGS and SUFU are consistent with my professional experience. I have used Boston Scientific pelvic mesh devices in my patients for many years with exemplary results and minimal complications. If polypropylene was not an appropriate biomaterial, I believe that I would see much higher rates of complications associated with the use of Boston Scientific's mesh devices designed to treat SUI.

VIII. Surgeons Do Not Expect Manufacturers to Provide Detailed Instructions on Mesh Removal.

Certain witnesses in this case also criticize Boston Scientific for not providing instruction regarding mesh removal following complications. I have experience with mesh removal and do not consider any "one size fits all" instruction or training to be feasible, practical, or appropriate. I have never seen any surgeon who learns how to address and treat complications associated with pelvic floor surgeries by consulting the DFU or other product literature. Rather, physicians learn how to treat complications through their own training and experience, consulting other physicians, and staying informed of developments in the relevant literature.

Treatment of complications evolves over time and is based on physician experience and preference. Any decision to remove pelvic mesh will be individualized and based upon physician and patient preference, the patient's risk tolerance, existing symptomology, and physical condition. I would not consult a DFU for such an individualized assessment, and I have not found a need to consult a DFU for the purpose of mesh removal.

[19] AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (Jan. 2014).

IX. Ms. Hanna Wilkerson

A. Overview

On March 9, 2010, Hanna Wilkerson, then-aged 57, underwent a cystoscopy, anterior colporraphy, and placement of a tension-free mid-urethral sling. Dr. Kelly Booth performed the surgery. Dr. Booth used the Advantage Fit Sling System to treat Ms. Wilkerson's SUI.

Ms. Wilkerson claims that implantation of the Advantage Fit sling caused her pain, urinary problems, persistent SUI and recurrent cystocele (prolapsed bladder), neuromuscular problems, nerve damage, and vaginal irritation. She claims that she will need to have pelvic floor reconstruction to address the reported issues. No doctor has recommended removal of the Advantage Fit device, and it has not been removed.

B. Relevant Medical and Personal History

Ms. Wilkerson is a 62-year-old female, Gravida 2, Para 2. She is currently unmarried and lives with her sister in Huntersville, North Carolina.

On January 28, 2010, Ms. Wilkerson presented to Dr. Booth with lower back pain, a "bulge," and progressive vaginal pressure and discomfort. According to Dr. Booth's note, Ms. Wilkerson had also previously noted urinary leakage with stress activities. Dr. Booth diagnosed a Grade 3 cystocele and probable urethrocele, and noted Ms. Wilkerson would likely require an anterior compartment repair and placement of a mid-urethral sling. Ms. Wilkerson is an EEG technician. Dr. Booth's January 28 record noted that Ms. Wilkerson's job frequently required her to move heavy equipment around a hospital. Regularly lifting and moving heavy equipment is a risk factor both for developing pelvic floor defects and for recurrence of SUI and POP after surgery if the patient does not wait long enough after surgery to resume this activity.

On February 12, 2010, Dr. Booth reviewed Ms. Wilkerson's urodynamic test results and diagnosed her with SUI. Dr. Booth presented options to treat Ms. Wilkerson's SUI and POP, discussed risks of pelvic floor surgery and risks specific to mesh implants, and answered Ms. Wilkerson's questions. Following this discussion, Ms. Wilkerson decided to undergo an anterior colporraphy, cystoscopy, and placement of a mid-urethral mesh sling. Ms. Wilkerson testified that prior to her surgery, her symptoms were interfering with her quality of life and her ability to perform her job.

C. Implant Surgery

Dr. Booth performed Ms. Wilkerson's surgery on March 9, 2010. Ms. Wilkerson signed an informed consent form. Dr. Booth implanted an Advantage Fit sling to address

Ms. Wilkerson's SUI and performed an anterior colporraphy to repair her cystocele. There were no complications during the surgery. Ms. Wilkerson was instructed not to perform any heavy lifting and to allow pelvic rest for six weeks after her surgery.

I believe that Ms. Wilkerson was an appropriate candidate for the Advantage Fit Sling System. Based on her symptoms, reported complaints, and physical condition, I believe that the benefits of this mesh implantation procedure outweighed any risks.

D. Post-Surgical Medical History

On March 24, 2010, Ms. Wilkerson presented to Dr. Booth's practice for a two-week post-operative follow-up appointment. Ms. Wilkerson was doing well and was not experiencing pain, but noted possible incomplete voiding. She did not complain about any other symptoms or complications.

On April 13, 2010, Ms. Wilkerson again reported doing well. Although she had some issues with incomplete voiding, she denied incontinence. She reported some tenderness on the left pubic symphysis, but Dr. Booth noted there was no evidence of mesh exposure.

On May 5, 2010, Dr. Booth noted that Ms. Wilkerson was still experiencing some tenderness on her left vaginal wall, but that this pain was improving, and there was no evidence of mesh erosion or migration. Ms. Wilkerson testified that she complained to Dr. Booth around this time that her surgery had been unsuccessful because she was still experiencing prolapse symptoms. Ms. Wilkerson's prolapse surgery did not involve mesh; it was an anterior colporraphy. Significantly, Ms. Wilkerson did not contend that her SUI symptoms returned or that the sling failed.

On October 26, 2010, Ms. Wilkerson complained of progressive pressure in her pelvis, accompanied by some left-sided suprapubic pain. Dr. Booth noted that Ms. Wilkerson was still moving EEG machines around the hospital, and expressed concern that this activity was causing the recurrent POP symptoms. However, Dr. Booth found good urethral support and no evidence of mesh erosion or other complications concerning the Advantage Fit procedure.

On November 18, 2010, Ms. Wilkerson again complained to Dr. Booth about recurrent bladder prolapse. Dr. Booth noted that Ms. Wilkerson's moving of EEG equipment at her job was "the likely etiology of the breakdown of the whole repair." Dr. Booth issued another note to Ms. Wilkerson's employer placing restrictions on her lifting and pushing heavy equipment.

During the November 18 visit, Dr. Booth also administered a trigger-point injection to treat continuing left-sided suprapubic tenderness. Even if attributable to the

Advantage Fit sling, this tenderness is a known and accepted complication of which Ms. Wilkerson should have been warned before her surgery. As explained below, however, Ms. Wilkerson's subsequent medical records and symptomology suggest that even this tenderness was unrelated to the Advantage Fit sling.

On December 9, 2010, Ms. Wilkerson presented to Dr. Bernard Taylor, a urogynecologist, reporting recurrent prolapse, vaginal bulging, progressive left groin discomfort, and slowed urine stream. Dr. Taylor diagnosed a recurrent Stage 3 cystocele. Ms. Wilkerson did not, however, report any SUI symptoms. I believe this further reinforces that her Advantage Fit placement was successful and free of complications. Furthermore, based on Ms. Wilkerson's symptoms and Dr. Taylor's record, I do not believe that Ms. Wilkerson's left-sided groin pain is attributable to the Advantage Fit sling. Dr. Taylor noted that Ms. Wilkerson had tenderness on the "left sidewall." None of the trocars for the Advantage Fit insert into the muscles of the left vaginal sidewall; in my clinical experience, I have never seen tenderness in the vaginal sidewall caused by the Advantage Fit sling. Therefore, I do not believe that Ms. Wilkerson's reported tenderness and discomfort was related to her mesh sling. I believe it is far more likely that Ms. Wilkerson's pain could be due to pelvic floor dysfunction that may have been caused by the failure of her anterior colporraphy and recurrent prolapse, or even the original colporraphy procedure itself. This opinion is supported by the examination performed by Dr. Taylor.

Although not reflected in her medical records, I note that Ms. Wilkerson contends in this case that she is suffering from nerve damage and numbness that she attributes to her Advantage Fit sling. In my opinion, any nerve damage that Ms. Wilkerson has suffered is not attributable to her mesh sling. If implantation of the Advantage Fit caused nerve entrapment or other neurological injury, Ms. Wilkerson's symptoms would have been immediate and severe; they would not progress slowly over time.

Finally, I note that Ms. Wilkerson contends that her recurrent prolapse is somehow attributable to her Advantage Fit sling. I am aware of no evidence to support the assertion that mesh slings cause recurrent prolapse. Ms. Wilkerson's prolapse was originally corrected with an anterior colporraphy, not a mesh device. In my opinion, there is no basis for contending that implantation of the Advantage Fit sling somehow caused recurrent prolapse. To the contrary, Ms. Wilkerson's medical records reflect that her recurrent prolapse was likely caused by her work duties, which including frequently lifting and pulling EEG equipment.

E. Concluding Opinions Concerning Ms. Wilkerson

Having reviewed Ms. Wilkerson's reported complications and analyzed all of her pertinent medical records and case materials, I do not believe that any of Ms. Wilkerson's alleged complications or symptoms are the result of any defect or inherent problem

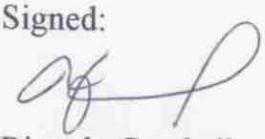
associated with the Advantage Fit product. To the contrary, I believe that Ms. Wilkerson's Advantage Fit sling worked as expected and has benefited her greatly in relieving SUI symptoms.

Ms. Wilkerson complains of pain, urinary problems, persistent SUI and recurrent cystocele, neuromuscular problems, nerve damage, and vaginal irritation. Each of these complaints falls within the scope of known and accepted potential complications, as listed in Boston Scientific's DFU. Moreover, as described above, most of the symptoms that Ms. Wilkerson reported after her implantation surgery have causes that I would not attribute to the mesh implantation.

I hold all of the above opinions to a reasonable degree of medical and scientific certainty.

I reserve the right to supplement or modify this report if new information, documents, or other materials become available.

Signed:



Ricardo Caraballo, M.D.

Date: 11/7/2014